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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/935,487	08/23/2001	Robert F. Rioux	BSCU-128/00US 027060-2694	1401
58249 7590 01/07/2009 COOLEY GODWARD KRONISH LLP ATTN: Patent Group Suite 1100 777 - 6th Street, NW WASHINGTON, DC 20001				
EXAMINER				
PELLEGRINO, BRIAN E				
ART UNIT		PAPER NUMBER		
3738				
MAIL DATE		DELIVERY MODE		
01/07/2009		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

**Application No.**

09/935,487

**Applicant(s)**

RIOUX ET AL.

**Examiner**

Brian E. Pellegrino

**Art Unit**

3738

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 01 October 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-4, 7, 8, 17-20 and 22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4, 7, 8, 17-20 and 22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/C)
- Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Claim Rejections - 35 USC § 103*

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-3,17-20,22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Maeda et al. (5507767) in view of Beyar et al. (5372600). Maeda et al. show (Fig. 8) a stent **30** for use within a body lumen comprising a coil segment **32** including a plurality of spaced windings. Maeda also discloses the stent is compressible and extendable, col. 4, lines 34-46. Please note the Examiner considers Claim 1 to include a product by process limitation "outer and inner layers adhered together to encapsulate" and should be noted that the product itself does not depend on the process for making it. Maeda illustrates the stent has a flexible sleeve or webbing **70** encapsulating the coil. Maeda discloses the stent can have distal and proximal portions with greater diameters than the middle portion, col. 5, lines 3-10. Maeda also discloses the sleeve or "webbing" is a polymer and sufficiently pliable to twist, col. 4, lines 49,54. However, Maeda fails to disclose at least one of the distal and proximal portions of the coil segment include a hook or explicitly the distance between windings. Beyar et al. teach a stent with hooks at both the proximal and distal ends of the coil body for connection to a delivery system, col. 7, lines 8-17. Beyar et al. also teach the distance between a coil winding of a stent placed in a vessel is at least about 0.5mm, col. 7, lines 5-7. It would have been obvious to one of ordinary skill in the art to space coil windings at least about 0.5mm and use

hooks as taught Beyar et al. with the stent of Maeda et al. such that the desired spacing between windings for flexibility can be established within the layers and the stent can be easily retained while delivering and released from the delivery system. Regarding claim 2, the Examiner is not interpreting "wire" to mean any specific type of material but a structural feature. Maeda clearly discloses (col. 3, line 21) a biocompatible material (polymer) and since it is a filament it is like a wire. The stent device is capable of being positioned coaxially within the body lumen of a patient. The apparatus is capable of use and of sufficient strength to maintain the urethra open. Maeda does disclose the length properties of the device can vary and is chosen to accommodate the need of the patient (col. 5, lines 8-15), thus the coil segment can be configured to extend from near the opening of a patient's bladder through the urethra and terminate before the sphincter.

Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Maeda et al. '767 in view of Beyar et al. '600 as applied to claim 2 and further in view of Lee (5123917). Maeda as modified by Beyar et al. is explained supra. However, Maeda in view of Beyar do not disclose the cross-sectional area of the wire to be  $0.0079\text{mm}^2$  to  $7.1\text{ mm}^2$ . Lee teaches a cross-sectional area of the wire that falls within the claimed range of  $0.0079\text{mm}^2$  to  $7.1\text{ mm}^2$  (col. 5, lines 59-61). It would have been obvious to one of ordinary skill in the art to use a cross-sectional area within  $0.0079\text{mm}^2$  to  $7.1\text{ mm}^2$  for the wire as taught by Lee for the wire filament coil of Maeda's stent as modified by Beyar et al. such that it has sufficient flexibility but also enough strength to maintain patency of the lumen.

Claims 7,8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Maeda et al. '767 in view of Beyar et al. '600 as applied to claim 1 and further in view of Hachtman et al. (5645559). Maeda as modified by Beyar et al. is explained supra. However, Maeda in view of Beyar do not disclose the polymer being a *low durometer* silicone within the range of 0-60D. Hachtman et al. teach that a silicone layer is placed on the stent to provide a barrier that prevents the growth of tissue through the stent and to support the flow of fluid through the lumen, col. 2, lines 14-18. Hachtman et al. also teach that low durometer silicone, such as 30D is placed on a stent, col. 4, lines 49-52. It would have been obvious to one of ordinary skill in the art to use a 30D silicone as taught by Hachtman et al. for the flexible sleeve on Maeda's stent as modified by Beyar et al. such that fluid flow is maintained through the lumen of the device while preventing tissue ingrowth.

### ***Response to Arguments***

Applicant's arguments with respect to claim 1 have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian E. Pellegrino whose telephone number is 571-272-4756. The examiner can normally be reached on M- F (7am-5:30pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TC 3700  
/Brian E Pellegrino/  
Primary Examiner, Art Unit 3738